

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

May 08, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 - Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada

88-0425691

(State or other jurisdiction of incorporation) (IRS Employer Identification Number)

3661 Horseblock Road

Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No \_

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company x

(Do not check if a smaller reporting company)

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes    No ☒

As of May 5, 2014, the Registrant had 9,564,264 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
March 31, 2014

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## PART I

## Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS  
AS OF

## - ASSETS -

	March 31, 2014 (Unaudited)	December 31, 2013
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$9,087,016	\$9,650,275
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$24,000 at March 31, 2014 and December 31, 2013, respectively	3,369,812	4,592,121
Inventories	3,604,603	3,188,726
Prepaid expenses and other current assets	1,118,818	1,099,379
<b>TOTAL CURRENT ASSETS</b>	<b>17,180,249</b>	<b>18,530,501</b>
 <b>FIXED ASSETS, net of accumulated depreciation</b>	 <b>1,872,341</b>	 <b>1,978,232</b>
 <b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	3,733,103	3,590,207
License agreements, net of current portion	300,000	326,875
Deposits on manufacturing equipment	43,388	16,410
Deposits and other assets	316,015	44,367
 <b>TOTAL ASSETS</b>	 <b>\$23,445,096</b>	 <b>\$24,486,592</b>

## - LIABILITIES AND STOCKHOLDERS' EQUITY -

## CURRENT LIABILITIES:

Accounts payable and accrued liabilities	\$3,268,469	\$4,309,490
<b>TOTAL LIABILITIES</b>	<b>3,268,469</b>	<b>4,309,490</b>

## COMMITMENTS AND CONTINGENCIES

## STOCKHOLDERS' EQUITY:

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 9,472,700 and 9,324,783 shares issued and outstanding for March 31, 2014 and December 31, 2013, respectively	94,727	93,248
Additional paid-in capital	47,097,811	46,875,026
Accumulated deficit	(27,015,911)	(26,791,172)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>20,176,627</b>	<b>20,177,102</b>

<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$23,445,096</b>	<b>\$24,486,592</b>
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See accompanying notes to condensed consolidated financial statements



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	For the three months ended	
	March 31, 2014	March 31, 2013
REVENUES:		
Net product sales	\$4,904,165	\$6,313,190
R&D, milestone and grant revenue	908,908	364,963
TOTAL REVENUES	5,813,073	6,678,153
Cost of product sales	3,540,462	3,984,263
GROSS MARGIN	2,272,611	2,693,890
OPERATING EXPENSES:		
Research and development expenses	1,197,622	1,045,259
Selling, general and administrative expenses	1,457,728	1,162,080
	2,655,350	2,207,339
(LOSS) INCOME FROM OPERATIONS	(382,739 )	486,551
OTHER INCOME (EXPENSE):		
Interest income	1,830	1,337
Interest expense	-	(335 )
	1,830	1,002
(LOSS) INCOME BEFORE INCOME TAXES	(380,909 )	487,553
Income tax (benefit) provision	(156,170 )	170,430
NET (LOSS) INCOME	\$ (224,739 )	317,123
Basic (loss) earnings per share	\$ (0.02 )	0.04
Diluted (loss) earnings per share	\$ (0.02 )	0.04
Weighted average number of shares outstanding, basic	9,339,181	8,062,984
Weighted average number of shares outstanding, diluted	9,339,181	8,699,209

See accompanying notes to condensed consolidated financial statements

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE THREE MONTHS ENDED**  
**(Unaudited)**

	March 31, 2014	March 31, 2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$7,035,382	\$6,220,808
Cash paid to suppliers and employees	(7,687,516)	(6,164,372)
Interest received	1,830	1,337
Interest paid	-	(335)
Net cash (used in) provided by operating activities	(650,304)	57,438
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(66,789)	(207,507)
Net cash used in investing activities	(66,789)	(207,507)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	153,834	17,955
Expenses from sale of common stock	-	(87,517)
Payment of loan obligation	-	(133,483)
Net cash provided by (used in) financing activities	153,834	(203,045)
<b>(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(563,259)</b>	<b>(353,114)</b>
Cash and cash equivalents - beginning of the period	9,650,275	2,951,859
Cash and cash equivalents - end of the period	\$9,087,016	\$2,598,745
<b>RECONCILIATION OF NET (LOSS) INCOME TO NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES:</b>		
Net (LOSS) Income	\$(224,739)	\$317,123
Adjustments:		
Depreciation and amortization	172,702	140,759
Deferred taxes	(142,896)	153,387
(Recovery of) doubtful accounts	-	(34,000)
Share based compensation	70,430	138,379
Changes in assets and liabilities:		
Accounts receivable	1,222,309	(423,345)
Inventories	(415,877)	(113,418)
Prepaid expenses and other current assets	(19,439)	(7,185)
Deposits and other assets	(271,773)	-
Accounts payable and accrued liabilities	(1,041,021)	(114,262)
Net cash (used in) provided by operating activities	\$(650,304)	\$57,438
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$16,410	\$208,134

See accompanying notes to condensed consolidated financial statements





CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2014  
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented 72 % of the Company's product revenues in the first three months of 2014. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 24 % of the Company's product revenues in the first three months of 2014. The Company also has other rapid tests that together represented approximately 4 % of sales in the first three months of 2014. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally. Chembio's products are sold under the Company's STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners. For example, the Clearview® label is owned by Alere, Inc. ("Alere"), which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's products that are currently being developed are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2013, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of March 31, 2014 and for the three-month periods ended March 31, 2014 and 2013, respectively, have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures, which are normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company's condensed consolidated financial position as of March 31, 2014, its condensed consolidated results of operations for the three-month periods ended March 31, 2014 and 2013, respectively, and its condensed consolidated cash flows for the three-month periods ended March 31, 2014 and 2013, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with ASC 605, which provides that revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. As of March 31, 2014 and December 31, 2013, respectively, all advanced revenues had been earned.

The Company follows Financial Accounting Standards Board ("FASB") authoritative guidance ("guidance") prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2014  
(UNAUDITED)

## c) Inventories:

Inventories consist of the following at:

	March 31, 2014	December 31, 2013
Raw materials	\$1,859,948	\$1,710,627
Work in process	642,487	464,481
Finished goods	1,102,168	1,013,618
	\$3,604,603	\$3,188,726

## d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding for the period. Diluted income per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2014 and 2013, have been included in the earnings per share computations:

	For the three months ended	
	March 31, 2014	March 31, 2013
Basic	9,339,181	8,062,984
Diluted	9,339,181	8,699,209

The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2014 and 2013, have been included in the diluted per share computations as the exercise prices of these securities were less than the stock price as of March 31, 2014 and 2013, respectively:

	For the three months ended	
	March 31, 2014	March 31, 2013
1999 and 2008 Plan Stock Options	-	636,225

There were 675,363 and 86,516 options outstanding as of March 31, 2014 and 2013, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended March 31, 2014 and 2013, respectively, because the effect would have been anti-dilutive as of March 31, 2014 and 2013, respectively.

## e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan ("SOP"). The total number of options available under the SOP was 375,000. As of March 31, 2014, there were 46,875 outstanding options under this SOP. No additional options may be issued under the SOP because it is more than 10 years after its adoption.

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), initially with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011, the Company's stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, non-incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of March 31, 2014, there were 245,262 options exercised, 504,738 options outstanding and 0 options or shares still available to be issued under the SIP.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2014**

(UNAUDITED)

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended March 31, 2014 and 2013 was \$5.39 and \$3.26 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is based on historical information.

The assumptions made in calculating the fair values of options granted during the periods indicated are as follows:

	For the three months ended	
	March 31, 2014	March 31, 2013
Expected term (in years)	6.3	4.8
Expected volatility	96.10%	100.91%
Expected dividend yield	0%	0%
Risk-free interest rate	1.52%	0.56%

The Company's results for the three-month periods ended March 31, 2014 and 2013 include share-based compensation expense totaling \$70,430 and \$138,379, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$3,046 and \$29,800, respectively), research and development (\$18,250 and \$39,912, respectively), and selling, general and administrative expenses (\$49,134 and \$68,666, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three-month periods ended March 31, 2014 and 2013 is based on the estimated fair value, at the date of issuance, of options outstanding, which is being amortized on a straight-line basis over the requisite service period for each vesting portion of the award, except for those that vested immediately and for which the estimated fair value was expensed immediately.

The following table provides stock option activity for the three months ended March 31, 2014:

	Number of	Weighted Average Exercise Price per	Weighted Average Remaining Contractual	Aggregate Intrinsic Value
Stock Options	Shares	Share	Term	
Outstanding at December 31, 2013	\$656,398	\$ 2.57	1.65 years	\$ 801,888
Granted	250,000	3.42		
Exercised	(147,917)	1.04		
Forfeited/expired/cancelled	-	-		
Outstanding at March 31, 2014	\$758,481	\$ 3.04	3.49 years	\$ 552,981
Exercisable at March 31, 2014	\$374,070	\$ 2.37	1.34 years	\$ 520,468

As of March 31, 2014, there was \$786,188 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 3.44 years. The total fair value of stock options vested during the three-month periods ended March 31, 2014 and 2013 was approximately \$40,388 and \$90,000, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
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f) Geographic Information:

U.S. GAAP establishes standards for the manner in which business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about products and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as "rapid medical tests". Management believes that it operates in a single business segment. Net product sales by geographic area are as follows:

	For the three months ended	
	March 31, 2014	March 31, 2013
Africa	\$831,462	\$847,322
Asia	51,047	19,266
Europe	36,059	7,605
North America	3,763,149	2,819,519
South America	222,448	2,619,478
	\$4,904,165	\$6,313,190

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
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g)Accounts Payable and Accrued Liabilities  
Accounts payable and accrued liabilities consist of:

	March 31, 2014	December 31, 2013
Accounts payable – suppliers	\$1,940,492	\$1,815,369
Accrued commissions	135,905	371,905
Accrued royalties / license fees	707,656	1,028,286
Accrued payroll	211,765	328,564
Accrued vacation	219,280	203,444
Accrued bonuses	-	317,372
Accrued expenses – other	53,371	244,550
TOTAL	\$3,268,469	\$4,309,490

NOTE3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a)National Institutes of Health (NIH) Grant:

In March 2011, the Company received a \$2.9 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned \$157,570 and \$192,000 for the three-month periods ended March 31, 2014 and 2013, respectively from this grant. The Company earned \$2,624,000 from this grant from inception through March 31, 2014, of which \$895,817 was paid to sub-contractors.

b)Battelle/CDC DPP® Influenza Immunity Test:

In April 2013, the Company entered into a follow-on, milestone-based development agreement of up to an additional \$472,000, resulting in a total amount of \$953,000, based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform (DPP®) technology. The agreement contemplates an additional period of approximately nine months in which the follow-on development activity is to be completed. The Company earned \$13,000 and none for the three-month periods ended March 31, 2014 and 2013, respectively from this agreement. The Company earned \$934,000 from this grant from inception through March 31, 2014.



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2014

(UNAUDITED)

NOTE 4 — LOANS PAYABLE:

On April 30, 2013, the Company entered into a new demand loan agreement ("Demand Note") with HSBC Bank, USA ("HSBC"). The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$2,000,000 outstanding at any one time. The accrued interest on the Demand Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. This is a demand note for which the bank lender can demand repayment of the entire loan, with accrued interest, at any time. The loan is subject to annual reviews, as well as an annual 30-day clean-up, during which there can be no amounts outstanding.

The HSBC Security Agreement, which is related to the Demand Note, contains covenants that place restrictions on the Company's operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, and restrictions on fundamental changes in the Company and in its business.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. As of March 31, 2014, nothing had been drawn down on the Demand Note.

NOTE 5 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement dated March 8, 2010 (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, \$0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights were distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

**Rights Initially Not Exercisable.** The Rights are not exercisable until a Distribution Date, which is defined below. Until a Right is exercised, the holder thereof, in his capacity as a holder of Rights, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

**Separation and Distribution of Rights.** The Rights will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15 % or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15 % or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i)

and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2014**

(UNAUDITED)

NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

The Company entered into an employment agreement effective March 13, 2014 ("Employment Agreement"), with Mr. Sperzel to serve as the Company's Chief Executive Officer, which included issuing incentive and non-incentive stock options to purchase 250,000 shares of the Company's common stock. Of these stock options, options to purchase 50,000 shares vest on each of the first five anniversaries of the effective date of the Employment Agreement. The exercise price for these options was to be equal to the volume-weighted average trading price for the Company's common stock on March 13, 2014, which was \$3.4163 per share. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the seventh anniversary of the effective date of the grant.

NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a)Economic Dependency:

The following table discloses product sales the Company had to each customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

	For the three months ended				Accounts Receivable	
	March 31, 2014		March 31, 2013		as of March 31, 2014	March 31, 2013
	Sales	% of Sales	Sales	% of Sales		
Customer 1	\$2,702,972	55	% \$2,589,954	41	% \$682,724	\$1,160,188
Customer 2	1,001,370	20	% *	*	519,300	*
Customer 3	*	*	1,218,875	19	% *	1,154,160
Customer 4	*	*	1,189,137	19	% *	1,189,147

(\*) Product sales did not exceed 10 % for the period indicated.

Note that sales include product sales only while accounts receivable reflects the total due from the customer, which includes freight.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2014  
(UNAUDITED)

The following table discloses purchases the Company made from each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

	For the three months ended			Accounts Payable	
	March 31, 2014	March 31, 2013	March 31, 2014	March 31, 2013	
	Purchases	% of Purc.	Purchases	% of Purc.	
Vendor 1	\$280,686	17	%	\$* *	\$145,950
Vendor 2	234,894	14	%	* *	\$142,626

(\*) Purchases did not exceed 10% for the period indicated

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration, United States Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2014

(UNAUDITED)

c) Employment Agreement:

The Company has employment contracts with three key employees. The contracts call for salaries presently aggregating \$929,500 per year. The Sperzel contract expires in March 2017, the Klugewicz contract expires in May 2015, the Esfandiari contract expires in March 2016 . In connection with the contract that expires in March 2017, the Company issued, in March 2014, 250,000 options to purchase common stock, with one-fifth vesting on each of the first five anniversaries of the grant. In connection with the contract that expires in May 2015, the Company issued, in May 2013, 5,000 options to purchase common stock, with one-half vesting on each of the first and second anniversaries of the grant. In connection with the contract that expires in March 2016, the Company issued, in March 2013, 30,000 options to purchase common stock, with one-third vesting on each of the first, second and third anniversaries of the grant.

NOTE                    8 — INCOME TAXES:

The Company's interim (benefit) for income taxes is estimated based on our calculated effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax (benefit) on a year-to-date basis and may change in subsequent interim periods. Our effective tax rate for the three-months ended March 31, 2014 was a benefit of 41.0 %. We calculated the current portion to be 8.5% of the (benefit), or \$(13,274), which was attributable to income tax (receivable) and the balance of \$(142,896) (increased) the carrying value of the deferred tax asset for the three months ended March 31, 2014.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The terms "Chembio", "Company," "we", "us", and "our" refer to Chembio Diagnostics, Inc. and its subsidiary as a consolidated entity, unless the context suggests otherwise.

### Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an ongoing basis we review our estimates and assumptions. Our estimates are based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 2013.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income are dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

All of the Company's future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of several products that employ the DPP® technology which are currently marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® HIV 1/2 –Syphilis Assay), or pursuant to private label license or distribution agreements such as those with the Oswaldo Cruz Foundation ("FIOCRUZ"), Labtest, RVR and Bio-Rad.

The Company has an active research and development program, including third-party funding from research and development contracts and grants, which offset increased research and development expenses. There are a number of projects under development that employ the DPP® technology, several of which are described below.

DPP® HIV Multiplex Antigen-Antibody Test - Development work continues on a DPP® HIV multiplex test that is designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, in whole blood samples. We believe that our development of such a test, combined with our patented DPP® point-of-care platform may better help identify HIV infections that cannot be identified by any of the currently FDA-approved rapid HIV tests. Such a test can better serve an unmet market need, and help to maintain and potentially grow the already strong position Chembio's products have in the U.S. rapid HIV test market.

DPP® Hepatitis-C (HCV) – Development work on our DPP® HCV point-of-care rapid test continues. Our development activity has been focused on creating a differentiated product that is at least capable of identifying antibody response in a more comprehensive manner than the currently available point-of-care test is able to do, and to also, in parallel, engage in efforts to differentiate those patients that are antibody positive from those that have an active infection, as up to 30% of patients that are HCV antibody-positive don't have an active infection.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States born between the years of 1945 and 1965 for HCV, which age cohort represents a substantial portion of the estimated over three million individuals in the United States that are infected with HCV infection, but unaware of their status. With a number of new anti-retroviral therapies approved, and even more anticipated pending approval in the years ahead by the FDA, we believe that over time, these new recommendations will be implemented. In fact, in May the United States Preventive Services Task Force revised its November 2012 recommendations to endorse the CDC recommendations by giving both hepatitis-C (HCV) screening for at-risk individuals and age-cohort screening a 'B' grade; under the Affordable Care Act, preventive services that have received an 'A' or 'B' grade from the USPSTF must be covered by insurance policies without cost-sharing, and be part of the essential health benefits for those individuals eligible for Medicare.

We are on track to complete development activities of the antibody detection assay in 2014, and to begin activities to commercialize product internationally, including U.S. regulatory submission in the U.S., by the end of 2015 or early 2016.

#### International Distribution & Manufacturing Agreements –

##### RVR

In February 2014, the Company entered into two agreements with RVR Diagnostics SDN BHD ("RVR"), a privately-held company in Malaysia. The agreements, which support Chembio's strategy of establishing a market presence in Asia, provide for collaboration with RVR as a licensee, distributor, and contract manufacturer. The agreements grant exclusive distribution rights to RVR in certain countries in the region and enable RVR to manufacture Chembio's DPP® HIV 1/2 Assay and Chembio's DPP® HIV-Syphilis Assay, as well as potentially other products developed by Chembio incorporating its patented DPP® technology.

The agreements consist of a technology transfer, license and distribution agreement ("License Agreement") and also a contract manufacturing agreement ("Manufacturing Agreement"). Under the License Agreement, the parties will collaborate to allow RVR to manufacture the licensed products so that distribution activities can begin in 2015. In consideration for this work, Chembio will receive a non-refundable signature fee and, approximately one year later, a contingent fee upon validation of the transfer activity milestones. RVR will distribute the products in the exclusive markets under license from Chembio subject to a royalty and continuing purchase of reagents. RVR is required to manufacture the DPP® HIV 1/2 Assay product in accordance with Chembio's FDA-approved specifications, RVR also plans to register its facility with the FDA.

The Manufacturing Agreement will enable Chembio to source products from RVR's facility for shipment to Chembio's customers that are outside RVR's exclusive territory. This will provide Chembio with a new, strategically located and cost-effective capacity that will be important in serving a number of global markets including the rapidly growing Asian markets.

##### Labtest

During the second quarter of 2013, Chembio entered into an international assembly and distribution agreement with Labtest Diagnostica SA (Labtest), a leading diagnostics manufacturer and marketing organization based in Brazil, for products based upon Chembio's patented Dual Path Platform (DPP ®) in Brazil and potentially other markets outside the U.S.

Pursuant to the agreement, Chembio will manufacture and sell certain specialized test components to Labtest and also will receive a royalty based on sales by Labtest of DPP ® products. Labtest will produce certain reagents and perform assembly and packaging operations in a dedicated space at Labtest's manufacturing facilities near Belo Horizonte, Brazil. Chembio will provide Labtest with the training necessary to perform the operations specific to the DPP ® products. Labtest will also have responsibility for marketing, promotion and distribution of the products in Brazil. All products will be marketed under brand names that will include Chembio's DPP ® trademark together with trade names selected by Labtest, and each test kit will state that Chembio Diagnostic Systems, Inc. is the licensor of the DPP ® trademark and technology. The products selected for inclusion in this agreement will address both private as well as public health markets, and will enable Chembio to participate in significant market opportunities in Brazil. This agreement addresses market opportunities that are independent of those addressed by Chembio's ongoing collaboration with the Oswaldo Cruz Foundation.



Labtest is on track with activities to qualify equipment and validate its processes, so that it can begin product registration activities for an initial group of infectious disease products, for commercial sale following regulatory approval.

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Sponsored Research & Development  
Multiplex Influenza Immunity Test –

During the second quarter of 2013, we reported that the Company had entered into a follow-on, milestone-based development agreement with a private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic influenza preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (CDC), for a multiplex, rapid, POC influenza immunity test utilizing Chembio's patented Dual Path Platform (DPP®) technology. The follow-on agreement was for up to approximately \$472,000 and activities were completed in January 2014 as anticipated. Discussions are ongoing regarding the provision of additional tests for clinical trials.

DPP® Febrile Illness Multiplex test – During the second quarter of 2013 we entered into a cooperative research project agreement with a U.S. government agency for up to \$750,000 for an eight-month development project. The project is to develop a rapid POC diagnostic test for five infectious diseases associated with febrile illness and to multiplex them into one assay. The project also contemplates that the test would be optimized for use with a mobile reader that incorporates cell phone technology to enable the results to be recorded, transmitted and monitored remotely via a cloud system, in real-time. This research project supports our efforts in developing multiplex products using our proprietary DPP® technology. Our DPP® technology, when combined with the mobile reader being used in the project, will enable real time data collection and monitoring capabilities. As these infectious diseases can all exhibit similar clinical symptoms, a rapid multiplex test that could distinguish them would be very useful, particularly in field conditions, so that correct diagnosis and treatment could be provided on a timely basis. We have completed R&D activities for this project as anticipated, and we currently are in discussions for the provision of 10,000 devices (5,000 of which have been provided, with an additional 5,000 to be provided in June), which will be used in a multi-center clinical trial in multiple countries, to make an assessment. Chembio also has an opportunity to explore commercial opportunities outside the scope of the government agreement.

DPP® Tuberculosis – In February 2011, we were awarded a three-year, \$2.9 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue our successful Phase I grant work to develop a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. During 2012, several additional antigens were identified to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. Antigen reagents have been finalized, and test prototype evaluation using well-characterized clinical specimens is in progress. Funding for the third and final year of this Phase II grant was confirmed with a reduction of approximately 1%.

Chembio's work to finalize DPP® assay design using various fusion proteins has been completed and production of an evaluation lot is in progress. These tests will be used for verification studies, internal and external evaluations at the selected collaborative sites (see below), QC protocol validation, and accelerated stability study. The target sensitivity is 80% and specificity is 95%. Study sites for external evaluations of DPP® assay include Bangladesh, Brazil, China, Haiti, Peru, Venezuela, and South Africa. The grant is expected to be completed by early July 2014, and is progressing on track.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors, we are discussing additional opportunities for sponsored research and development activity. We endeavor to select sponsored research projects where we believe there is an identifiable commercial opportunity and/or where other benefits to the Company are anticipated in connection with these projects.

In general, we are considering certain new DPP® product opportunities, either as OEM development projects and/or as Chembio-branded products. These products are being identified based upon our assessment of opportunities in the market and upon whether they can be addressed with our proprietary technology, along with our development and manufacturing capabilities and experience. We are also identifying and assessing additional technologies that we believe can enhance or expand our current product portfolio, and thereby provide additional revenue streams, although there is no assurance that we will be able to obtain or utilize any of them profitably.

### Regulatory Activities

CE Mark for FDA-approved HIV tests – In March 2014, Chembio's HIV 1/2 STAT-PAK® Assay received CE Mark approval from European regulators. The Chembio HIV 1/2 STAT-PAK® Assay is now cleared for commercialization within the European Union for rapid, POC detection of HIV. Chembio is currently working with commercialization partners in Europe.

FDA Approval for DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples – We received FDA approval of our Pre-Marketing Application (PMA) for this product on December 19, 2012 as we previously announced. The CLIA waiver was submitted in November 2013, and in February 2014 we received a letter from the FDA on the current status of review of our CLIA waiver application. The FDA determined that additional information is needed to complete its review of the Company's DPP® HIV 1/2 Assay CLIA waiver application. Since that time, we have had multiple discussions with the FDA, and it was determined that no additional clinical studies will be required. Additional in-house laboratory studies will be required for the FDA to complete its review of the application for CLIA waiver, and we anticipate that an update to our CLIA timeline can be provided, pending information from the FDA regarding such studies.

DPP® HIV-Syphilis – We have developed this product for international and US marketing. For the international market, the product has been registered in Mexico. We have submitted this product both for evaluation by the CDC, acting on behalf of the United States Agency of International Development, and the WHO, which has accepted this product to be evaluated for pre-qualification in its global procurement scheme.

We are currently in discussions with the FDA re: the clinical studies that will be required for PMA submission, and we anticipate that an update to our timeline can be provided, pending information from FDA regarding the clinical algorithm that will be used to assess the syphilis component performance of the assay.

There can be no assurance that any of the aforementioned Research & Development and/or Regulatory products or activities will result in any product approvals or commercialization, nor that any of the existing research and development activities, or any new potential development programs or collaborations will materialize or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

### Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2013, see our Annual Report on Form 10-K for the twelve months ended December 31, 2013, which was filed with the SEC on March 6, 2014.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2014 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2013

Income:

For the three months ended March 31, 2014, Loss before income taxes was \$(381,000) compared to Income before taxes of \$487,000 for the three months ended March 31, 2013. Net Loss for the 2014 period was (\$225,000) as compared to a Net Income of \$317,000 for 2013. The decrease in net income is primarily attributable to a decrease in product sales. Gross margin decreased in the three months ended March 31, 2014 as compared with the three months ended March 31, 2013, by \$421,000, or 15.6%. This decreased gross margin included increased operating expenses, the most significant of which was an increase in wages and related expenses of \$310,000, which accounted for most of the change from a net income to a net loss.

Revenues:

Selected Product Categories:	For the three months ended			
	March 31, 2014	March 31, 2013	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$3,536,699	\$4,934,154	\$(1,397,455)	-28.32 %
DPP Tests and Components	1,168,770	1,142,835	25,935	2.27 %
Other	198,696	236,201	(37,505 )	-15.88 %
Net Product Sales	4,904,165	6,313,190	(1,409,025)	-22.32 %
License and royalty revenue	160	-	160	100.00 %
R&D, milestone and grant revenue	908,748	364,963	543,785	149.00 %
Total Revenues	\$5,813,073	\$6,678,153	\$(865,080 )	-12.95 %

Revenues for our lateral flow HIV tests and related components during the three months ended March 31, 2014 decreased by approximately \$1,397,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately \$2,397,000. These decreases were partially offset by increased sales to Mexico of \$793,000 and increased sales to Alere from \$2,590,000 during the three months ended March 31, 2013 to \$2,703,000 during the three months ended March 31, 2014. Revenues for our DPP® products during the three months ended March 31, 2014 increased by approximately \$26,000 over the same period in 2013. The increase in R&D, and in milestone and grant revenue, was primarily due to \$750,000 in revenue from the license contract we signed in February with RVR Diagnostics. This was partially offset by a reduction in revenue from certain development projects that are nearing completion. R&D revenues include funds, recognized on an "as expenses are incurred" basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis, which was effective March 1, 2011, as well as a development contract with Battelle entered into in the fourth quarter of 2012.

Gross Margin:

Gross Margin related to Net Product Sales:	For the three months ended			
	March 31, 2014	March 31, 2013	\$ Change	% Change
Gross Margin per Statement of Operations	\$2,272,611	\$2,693,890	\$(421,279)	-15.64 %
Less: R&D, milestone, grant, license and royalty revenues	908,908	364,963	543,945	149.04 %
Gross Margin from Net Product Sales	\$1,363,703	\$2,328,927	\$(965,224)	-41.44 %
Product Gross Margin %	27.81 %	36.89 %		

The gross margin dollar decrease of \$421,000 included a \$965,000 decrease in gross margin from product sales and was partially offset by a \$544,000 increase in non-product revenues. The decrease in product gross margin of \$965,000 is primarily attributable to the lower product sales and lower production compared to 2013. The product gross margin decrease is comprised of two components, one is the decrease in product sales of \$1,409,000, which at the 27.8% margin percentage contributed \$392,000 to the decrease, and second, the decreased change in margin percentage of 9.1% contributed to the balance (\$573,000) of the decrease in our product gross margin. The 9.1 % decrease in the percentage, from 36.9% in 2013 to 27.8% in 2014, was primarily due to a larger amount of unapplied overhead, along with an increase of royalty expense of 0.7% of product sales. As a result of the lower volume of products produced in the first quarter of 2014, the Company wasn't able to cover the relatively fixed overhead items, such as rent, supervision, etc., because they were spread over a lesser number of products, thereby increasing their cost.

Research and Development:

Research and development expenses include costs incurred for product development, regulatory approvals, clinical trials, and product evaluations.

Selected expense lines:	For the three months ended			
	March 31, 2014	March 31, 2013	\$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	\$106,143	\$105,491	\$652	0.62 %
Consulting	2,419	17,726	(15,307 )	-86.35 %
Stock-based compensation	2,425	11,605	(9,180 )	-79.10 %
Clinical trials	120,783	97,776	23,007	23.53 %
Other	18,244	4,349	13,895	319.50 %
Total Regulatory	250,014	236,947	13,067	5.51 %
R&D Other than Regulatory:				
Wages and related costs	567,774	507,795	59,979	11.81 %
Consulting	44,550	9,837	34,713	352.88 %
Stock-based compensation	15,825	28,307	(12,482 )	-44.10 %
Materials and supplies	236,158	181,184	54,974	30.34 %
Other	83,301	81,189	2,112	2.60 %
Total other than Regulatory	947,608	808,312	139,296	17.23 %

Total Research and Development \$1,197,622 \$1,045,259 \$152,363 14.58 %

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2014 increased by \$13,000 as compared to the same period in 2013. This was primarily due to an increase of \$23,000 in clinical trial expenses partially offset by a reduction in consulting.

R&D expenses other than Clinical & Regulatory Affairs increased by \$139,000 in the three months ended March 31, 2014, as compared with the same period in 2013. The increases were primarily related to an increase in wages and related costs, and in material and supplies, to support our sponsored research and internal development programs.

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Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended				
	March 31, 2014	March 31, 2013	\$ Change	% Change	
Wages and related costs	\$690,502	\$441,472	\$249,030	56.41	%
Consulting	103,747	6,200	97,547	1573.34	%
Commissions	30,435	159,908	(129,473)	-80.97	%
Stock-based compensation	49,134	68,666	(19,532)	-28.44	%
Marketing materials	23,985	6,963	17,022	244.46	%
Investor relations/investment bankers	46,832	74,863	(28,031)	-37.44	%
Legal, accounting and compliance	212,980	240,057	(27,077)	-11.28	%
Travel, entertainment and trade shows	39,548	27,751	11,797	42.51	%
Bad debt allowance (recovery)	-	(33,450)	33,450	-100.00	%
Other	260,565	169,650	90,915	53.59	%
Total S, G & A	\$1,457,728	\$1,162,080	\$295,648	25.44	%

Selling, general and administrative expenses for the three months ended March 31, 2014, increased by \$296,000 as compared with the same period in 2013, a 25% increase. Significant increases in wages and related costs, which for 2014 included the COO not included in 2013, consulting, and the cost of the CEO search and related expenses (reflected in Other above) were partially offset by a decrease in commissions due to decreased sales to Brazil along with a decrease in investor relations/investment bankers, and a decrease in professional fees.

Other Income and (Expense):

	For the three months ended				
	March 31, 2014	March 31, 2013	\$ Change	% Change	
Interest income	\$1,830	\$1,337	\$ 493	36.87	%
Interest expense	-	(335)	335	-100.00	%
Total Other Income and (Expense)	\$1,830	\$1,002	\$ 828	82.63	%

Other income for the three months ended March 31, 2014 increased approximately \$1,000, to an income of \$2,000 from an income of \$1,000 in the same period in 2013, as a result of an increase in interest income and a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the three months ended March 31, 2014 the Company recognized a \$156,000 income tax benefit and increased its deferred tax assets by \$143,000. The Company maintains a full valuation allowance on research and development tax credits.

## MATERIAL CHANGES IN FINANCIAL CONDITION

## Selected Changes in Financial Condition

	As of			
	March 31,	December		%
	2014	31, 2013	\$ Change	Change
Cash and cash equivalents	\$9,087,016	\$9,650,275	\$(563,259)	-5.84 %
Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$24,000 at March 31, 2014 and December 31, 2013, respectively	3,369,812	4,592,121	(1,222,309)	-26.62 %
Inventories	3,604,603	3,188,726	415,877	13.04 %
Fixed assets, net of accumulated depreciation	1,872,341	1,978,232	(105,891)	-5.35 %
Deposits and other assets	316,015	44,367	271,648	612.27 %
Deferred tax asset, net of valuation allowance	3,733,103	3,590,207	142,896	3.98 %
Accounts payable and accrued liabilities	3,268,469	4,309,490	(1,041,021)	-24.16 %

Cash decreased by \$563,000 from December 31, 2013, primarily due to net cash used in operating activities for the first quarter of 2014. In addition there were decreases in accounts receivable, net of allowance, of \$1,222,000, fixed assets of \$106,000 and accounts payable and accrued liabilities of \$1,041,000. We experienced increases in inventories of \$416,000, deposits and other assets of \$271,000 and deferred taxes of \$143,000.

The decrease in accounts receivable was primarily attributable to the lower amount of credit sales at the end of March 2014 versus December of 2013. The increase in inventories is due to production for orders received to be shipped in the second quarter of 2014. The decrease in fixed assets is primarily due to depreciation. The increase in deposits and other assets is due to additional rental deposits and related capitalized expenses. Deferred tax asset increase is related to the provision for income tax benefit.

## LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	March 31,	March 31,		%
	2014	2013	\$ Change	Change
Net cash (used in) provided by operating activities	\$(650,304)	\$57,438	\$(707,742)	-1232.18 %
Net cash used in investing activities	(66,789)	(207,507)	140,718	-67.81 %
Net cash provided by (used in) financing activities	153,834	(203,045)	356,879	-175.76 %
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	\$(563,259)	\$(353,114)	\$(210,145)	59.51 %

The Company's cash decreased by \$563,000 from December 31, 2013, primarily due to net cash used in operating activities for the first quarter of 2014.

The cash used in operations in 2014 was \$650,000, primarily due to a reduction in accounts payable and other accrued liabilities of \$1,041,000, an increase in inventories of \$416,000, an increase in deposits and other assets of \$272,000, an increase in prepaid and other current assets of \$19,000, and a net loss net of non-cash items of \$124,000, which were partially offset by a decrease in accounts receivable of \$1,222,000. Net loss net of non-cash items includes net loss of \$225,000, \$143,000 in benefit for income taxes, partially offset by \$173,000 in depreciation and amortization, and \$70,000 in share-based compensation. The use of cash from investing activities is primarily the purchase of fixed assets. The increase in cash from financing activities was proceeds from option exercises.

The decrease in cash from operations in 2013 was \$353,000, primarily due to net cash used in investing and financing activities and was partially offset by net income net of non-cash items of \$716,000 which was partially offset by an increase in accounts receivable of \$423,000 along with an increase of \$113,000 in inventory, a decrease of \$114,000 in accounts payable and accrued liabilities, and other items aggregating \$7,000. Net income net of non-cash items includes net income of \$317,000, \$141,000 in depreciation and amortization, \$138,000 in share-based compensation, and \$153,000 in provision for deferred taxes, partially offset by \$34,000 in recovery of doubtful accounts. The use of cash from investing activities is primarily the purchase of fixed assets. The decrease in cash from financing activities



was due primarily to the payment of a loan obligation along with expenses from the sale of common stock partially offset by proceeds from option exercises.

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#### Fixed Asset Commitments

As of March 31, 2014, the Company had paid deposits on various pieces of equipment aggregating \$43,388, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has commitments for \$71,530 in additional equipment purchase obligations.

#### RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

2014 will be a pivotal year for Chembio, at every level of the organization. In March 2014, we named John J. Sperzel III as the Company's new Chief Executive Officer and President. Mr. Sperzel comes to Chembio with an impressive track record in building point-of-care (POC) diagnostic companies and he has created successful commercialization teams for a number of prominent companies in our industry. His leadership, energy level and experience in the POC diagnostics market will drive Chembio's new business strategy and future growth.

With a new focus on commercialization, Chembio is building an internal sales and marketing organization to serve end-user customers and distribution partners. We are on track with this important investment, having hired a number of experienced professionals to lead this directive, including a director of sales and a senior director of marketing. Due to the variability in purchasing levels that we often see in this sector, our first quarter sales fell short of expectations. Our commercial investments are aligned with our objective to improve sales performance and predictability. We believe the strategy to build a Chembio brand in the U.S. will be successful.

The Chembio DPP® HIV 1/2 Assay, which received FDA approval in December 2012 for use with oral fluid or blood samples, will be a cornerstone of our Chembio branding efforts in the United States. We have had productive communications with the FDA regarding the CLIA waiver application for our DPP® HIV 1/2 Assay. While prior feedback from the FDA indicated that additional clinical studies may be required, the FDA recently agreed to complete the review of the CLIA waiver application based upon data from additional laboratory studies, which will be conducted at Chembio. We believe this development will accelerate our time to market with this product from what we had anticipated based on the original FDA feedback.

Another key development during the first quarter was Chembio's decision to terminate the STAT-PAK® U.S. distribution agreement with Alere. We are confident in this decision.

On the international front, we continue to pursue and develop successful private label license and distribution agreements in a number of markets, such as we have done in Latin America (FIOCRUZ, Labtest, SAVI) and Asia (RVR).

We believe 2014 will be a transformative year under the leadership of our new Chief Executive. We are committed to building the Chembio brand in the U.S. and to providing customers with high-quality, reliable products. We are investing in our commercial organization, new product development, manufacturing, and regulatory initiatives in order to realize our long-term strategic plan. We believe these investments will significantly increase shareholder value.

ITEM 4. CONTROLS AND PROCEDURES

- Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer,
- (a) concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

- Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15
- (b) under the Exchange Act that occurred during the Company's first three months of fiscal 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

At the time of John J. Sperzel III's joining the Company as Chief Executive Officer on March 13, 2014, the Company granted to Mr. Sperzel options to purchase 250,000 shares of the Company's common stock. 43,132 of the Options were intended to be incentive stock options under the Company's 2008 Stock Incentive Plan (the "Plan") and within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, and 206,868 of the Options were intended to be non-qualified stock options not covered by the Plan because there were no unissued options available for grant under the Plan. Resales of shares of common stock underlying the incentive stock options will be covered by the Company's registration statement on Form S-3; resales of shares of common stock underlying the non-qualified stock options will not be covered by the S-3 registration statement. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. No cash was exchanged in this issuance; the options were issued as consideration for Mr. Sperzel's employment. Subject to the terms and conditions of the employment agreement, 50,000 of the options will become exercisable on each of the first five anniversaries of the date the options were granted, and all the options will expire on the seventh anniversary of the date the options were granted unless exercised prior to that date. Mr. Sperzel is an accredited investor as defined in the regulations promulgated under the Securities Act of 1933.

ITEM 6. EXHIBITS

EXHIBITS INDEX

Number Description

- 3.1 Articles of Incorporation, as amended. (1)
- 3.2 Amended and Restated Bylaws. (2)
- 4.1\* Form of Employee Option Agreement. (3)
- 4.2 1999 Equity Incentive Plan. (4)
- 4.3 2008 Stock Incentive Plan. (5)
- 4.4 Form of Option, for 2008 Stock Incentive Plan.
- 4.5 Rights Agreement, dated March 8, 2010 (6)
- 4.6 Form of Warrant (to be filed by amendment) [to be revised]
- 10.1\* Employment Agreement dated March 13, 2014 with John J. Sperzel III
- 10.2\* Employment Agreement dated March 5, 2013 with Javan Esfandiari (10).
- 10.3\* Employment Agreement dated May 22, 2013 with Sharon Klugewicz (12)
- 10.3 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (8)
- 10.4 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
- 10.5 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
- 10.6 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (8)
- 10.8 Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
- 10.9 Loan and Security Agreement, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
- 14.1 Ethics Policy (9)
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Definition Linkbase Document
- 101.LAB XBRL Taxonomy Label Linkbase Document
- 101.PRE XBRL Taxonomy Presentation Linkbase Document

- 1 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
- 2 Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
- 3 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
- 4 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
- 5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
- 6

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Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.

7 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.

8 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.

9 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.

10 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.

11 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 25, 2013.

12 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.

(\*) An asterisk (\*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: May 8, 2014 By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 8, 2014 By: /s / Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)